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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,720	06/29/2001	Wen-Yuan Song	5853-173	8728

7590

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/14/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/896,720	SONG ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6 and 7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-7, 19 and 20, in Paper No. 9 is acknowledged.
2. Claims 8-18 and 21-24 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
3. This application contains claims 8-18 and 21-24 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).
5. The information disclosure statements filed 7 January 2002 and 5 March 2002 have been considered, signed copies are attached hereto.

Drawings

6. The drawings in this application are objected to by the Draftsperson as informal. See the attached PTO-948 form. Applicant is reminded that correction of the drawings

cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.

Claim Objections

7. Claim 2 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, a polynucleotide that hybridizes under high stringency conditions because "high stringency" is ill-defined as discussed below, to the nucleotide sequence of SEQ ID NO: 1 would be broader in scope than a nucleotide sequence with 80% identity to SEQ ID NO: 1.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 7 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Specifically the claimed cell does not sufficiently distinguish over cells as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to

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indicate the hand of the inventor, e.g., by stating -- the purified nucleic acid of claim 1 --.

The claim as presently worded reads on any rice cell. See MPEP § 2105.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1-7 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, line 3, and claim 19, line 6, the phrase "at least one functional activity of native XB3" is indefinite because it is unclear what the metes and bounds of this phrase is. Applicant's teachings at page 3, lines 13-18 of the specification appears to define the functional activity as purified protein whose amino acid sequence is SEQ ID NO: 2, which is a physical characteristic and not a functional characteristic.

At claim 2, line 2, the phrase "high stringency conditions" is indefinite because the teachings of the specification at page 5, lines 31-32, do not define wash times or number that would properly define the limitation "high stringency conditions", thus it is unclear what the metes and bound of the claimed invention are.

At claim 4, the designation "XA21" is indefinite because the designation appears to be arbitrary. It is unclear what the metes and bounds of an "XA21" are wherein the protein encoded by the purified nucleic acid of claim 1 specifically binds.

Claims 3 and 5-7 are also indefinite because said claims do not obviate the indefiniteness of the claim(s) upon which they depend.

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12. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 2, 4-7, 19 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a nucleic acid comprising a nucleotide sequence that encodes a naturally occurring protein that shares at least 80% sequence identity with SEQ ID NO: 2 and has at least one functional activity of native XB3, a nucleic acid that hybridizes under high stringency conditions with the nucleotide sequence of SEQ ID NO: 1, a vector comprising said nucleic acid, a cell comprising said nucleic acid and a method of modulating disease in a plant cell or seed comprising introducing into the plant cell or seed said purified nucleic acid that encodes a naturally occurring protein that shares at least 80% sequence identity with SEQ ID NO: 2, wherein said protein has at least one functional activity of native XB3 and lacks at least one functional activity of native XB3.

Applicant describes an ubiquitin ligase designated XB3 having the amino acid sequence of SEQ ID NO: 2. Applicant also describes that the ubiquitin ligase carries out the ubiquitination of XA21 (see paragraph spanning pages 36-37, for example). Applicant also describes that complete XB3 ubiquitin ligase protein is required to carry out ubiquitination of XA21 (see page 37, 2nd paragraph of the specification).

Applicant does not describe purified nucleic acids that encode a protein that shares at least 80% sequence identity with SEQ ID NO: 2 and has at least one functional activity of native XB3, or said purified nucleic acids that hybridize under high stringency conditions to the nucleotide of SEQ ID NO: 1.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case, Applicant has failed to describe the correlation between the function of the encoded protein and the structure of the nucleic acid sequence as broadly claimed.

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The art teaches that ubiquitin ligase enzymes are highly specific for the substrate with which they interact (see Tyers *et al* 1999, Science 284(5414):601-604, especially the first paragraph on page 601). In addition, Tyers teaches that one of skill in the art cannot inherently describe an ubiquitin E3 ligase without empirical evidence, of which Applicant's XB3 is an example, based on the structure of the gene or the protein, or the functional characteristics of the protein (see page 603, right column, 3rd paragraph).

14. Claims 1-7, 19 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a nucleic acid comprising a nucleotide sequence that encodes a naturally occurring protein that shares at least 80% sequence identity with SEQ ID NO: 2 and has at least one functional activity of native XB3, a nucleic acid that hybridizes under high stringency conditions with the nucleotide sequence of SEQ ID NO: 1, a vector comprising said nucleic acid, a cell comprising said nucleic acid and a method of modulating disease in a plant cell or seed comprising introducing into the plant cell or seed said purified nucleic acid that encodes a naturally occurring protein that shares at least 80% sequence identity with SEQ ID NO: 2, wherein said protein has at least one functional activity of native XB3 and lacks at least one functional activity of native XB3.

Applicant teaches an ubiquitin ligase designated XB3 having the amino acid sequence of SEQ ID NO: 2. Applicant also teaches that the ubiquitin ligase carries out the ubiquitination of XA21 (see paragraph spanning pages 36-37, for example).

Applicant also teaches that complete XB3 ubiquitin ligase protein is required to carry out ubiquitination of XA21 (see page 37, 2nd paragraph of the specification).

Applicant does not teach purified nucleic acids that encode a protein that shares at least 80% sequence identity with SEQ ID NO: 2 and has at least one functional activity of native XB3, or said purified nucleic acids that hybridize under high stringency conditions to the nucleotide of SEQ ID NO: 1. In addition, Applicant's teachings of the effect of suppressing XB3 levels in a plant appear contradictory (see pages 42 and 43 of the specification as addressed below), and hence Applicant does not teach how to use the claimed nucleic acids, vectors and cells, and does not teach a method of modulating disease resistance in a plant.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided no guidance on how to make and use isolated nucleic acids encoding a protein having at least 80% sequence identity with SEQ ID NO: 2. In addition, Applicant has provided limited guidance for using a nucleic acid encoding the amino acid sequence of SEQ ID NO: 2 for modulating disease resistance in any plant cell or seed as broadly claimed. The state of the art has been discussed in the previous

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rejection as related to the teachings of Tyers *et al* (1999), that ubiquitin ligases are highly substrate specific and that one of skill in the art cannot inherently associate specific function simply based to structural characteristic of the nucleic acid or the encoded protein. Hence, given the limited guidance by Applicant, the nature of the invention and the state of the art at the time of Applicant's invention, it would have required undue trial and error experimentation to identify and isolate a myriad of nucleic acids that encode a naturally occurring protein that has at least one functional activity of native XB3 and shares at least 80% sequence identify with SEQ ID NO: 2 and to use such an isolated nucleic acid to modulate disease resistance in a plant cell or seed as broadly claimed.

At claims 19 and 20, Applicant's guidance is limited to a method in rice. The target substrate protein, XA21, of XB3 appears to be only present in rice and associated with a disease response in rice, and is not generally applicable to any plant as broadly claimed. In addition, the examples Applicant provides on pages 42 and 43 appear contradictory, because in both examples, Applicant suppressed levels of XB3 in a rice plant a produced opposite phenotypes, one being hypersensitive and one being "resistant", non-hypersensitive, to a rice pathogen (see page 42, lines 16-19, and page 43, lines 6-9 of the specification). In addition, Applicant's use of the term "resistant lines" appears to be directed to resistance to the hypersensitivity reaction induced by the pathogen, while in Applicant's earlier study cited on page 42, line 33, of the specification, Applicant defines "resistant lines", which overexpress the XA21 protein, to have the opposite meaning (see Song *et al* 1995, Science 270:1804-1806, especially

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page 1805, right column). In both examples, the levels of XB3 are taught as reduced in both the “susceptible” and the “resistant” lines. In addition, in the example in the paragraph spanning pages 41-42 of the specification, Applicant states that one transgenic plant that does not carry XA21::MYC formed spontaneous lesions, thus if the formation of spontaneous lesions appears independent of the presence of XA21. Conversely, at page 43, lines 3-4, Applicant teaches that the resistant lines had easily detected XA21::MYC expression. The specification speculates that expression of XA21 is related to a hypersensitivity response to *Xanthomonas* pathogens, and that XB3 negatively regulates this hypersensitivity reaction by regulating XA21 activity in the rice cell (page 2, 2nd paragraph of the Remarks). Hence, it is unclear from the instant specification how is one of skill in the art to predictably use the taught nucleic acid encoding SEQ ID NO: 2 to predictably modulate disease resistance in a plant cell or seed as broadly claimed without undue trial and error experimentation.

Conclusion

15. Claims 1-7, 19 and 20 are free of the prior art which does not teach nor fairly suggest a purified nucleic acid that encodes the XB3 protein of SEQ ID NO: 2, or a method of modulating disease in a rice plant using said nucleic acid. .

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
7 January 2003

AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.